IN THE DRAWINGS

The drawings have been objected to under 37 C.F.R. § 1.83 as failing to show every feature of the invention specified in the claims. Specifically, the "radial indenture" appearing in claim 2 is said not to be shown. The "radial indenture" recited by Applicant was intended to comprise the slot for receiving a screw driver, ref. no. 9 in Fig. 1. However, because of the ambiguity in the claim language, claim 2 has been cancelled, and that feature has been incorporated into new claim 9 as being a "slotted recess." Accordingly, as the "radial indenture" has been cancelled and replaced, the Examiner is respectfully requested to withdraw his objection to the drawings.

REMARKS

In the Office Action the Examiner rejected claims 1 through 5 and 7 under 35 U.S.C. § 103(a) as being anticipated by U.S. Patent No. 6,436,142 to Pais. Claims 1 through 8 were found to be obvious over Pais in view of U.S. Patent No. 2,381,050 to Hardinge.

The claims have been canceled and new claims 9 and 10 have been added. New claim 9 includes substantially all limitations previously found in claims 1 – 5 and 7 – 8, but has been rewritten to provide clarity and avoid potential ambiguity that may have been introduced through the translation of the original Portuguese language priority document. As rewritten, new claim 9 is believed to distinguish over cited prior art of record. Claim 10 depends from new claim 9, and includes the limitations of cancelled claim 6.

For the convenience of the Examiner, and to provide additional clarity to this Response and Amendment, references to the paragraphs of the specification filed herein shall be made by indicating the paragraph number in the specification as shown in the published version of the application, Pub. No. 2002/0147454 A1, a copy of which is appended to this Response and Amendment.

Newly added claim 9 finds support in the specification as indicated in the following recitation of the claim:

> Claim 9. A surgical screw for the connection of human bone structures comprising:
>
> an expandable element and a spindle,
>
> said expandable element prior to expansion having a substantially cylindrical configuration [0015] comprising a finely threaded external surface along the length of said cylindrical configuration [0020, Figs. 1 & 2], said threads being substantially continuous [0020, Fig. 1] such that said expandable element may be inserted into a cylindrical cavity in a bone by imparting a turning motion upon said expandable element [0025] whereby said threads will frictionally and nondestructively engage the walls of said cavity to position said expandable element within said cavity [0018],

said expandable element further comprising a distal portion [0016] and a proximal portion [0018], said proximal portion terminating at a flat end [Fig. 2], said flat end having a slotted recess [Fig. 1, ref. no. 9] suitable for accepting a tool having a blade for turning said expandable element during emplacement[0018],

said distal portion comprising four or more longitudinally extending expandable members [Fig. 1], said expandable members prior to expansion being positioned in close proximity to one another to form a substantially cylindrical surface having same diameter as said proximal portion [0015, Fig. 1] and substantially maintaining the continuity of said threads comprising said finely threaded external surface [0020, Fig. 1], said expandable members having longitudinally extending slots between them [0017, Fig. 1], said slots extending from the distal end of said distal portion to a point near the midpoint of said expandable element [0017], said distal end being truncated to form a smooth conical frustum [0025, Figs. 1, 2, 3],

said expandable element further comprising a threaded axial bore extending longitudinally through said expandable element [0016, Fig. 2], said threaded axial bore having a constant diameter from said proximal end to a point near the midpoint of said axial bore[0022], said axial bore forming a funnel portion of continuously decreasing diameter beginning near said midpoint of said axial bore and having a minimum diameter at said distal end of said axial bore [0016, Fig. 2],

said spindle comprising a central shaft and a head [0019], said shaft being threaded along its length (Fig. 1] and smoothly engaging said threaded axial bore within said proximal portion upon imparting a turning motion to said spindle [0021, 0022, Fig. 2], said shaft thereafter increasingly extending into said funnel portion of said axial bore upon the continued turning of said spindle within said axial bore, said shaft continuously forcing said expandable members to spread apart from one another as said shaft is continuously extended within said funnel portion [0023, Fig. 3],

said spreading movement of said expandable members continuously increasing the effective diameter of said distal portion of said expandable element as said shaft is further extended into said funnel portion [0023, Fig. 3], thereby causing said expandable element to be securely anchored within said cavity without destructively engaging said bone forming said cavity [0023],

said head of said spindle having a diameter that is smaller than the diameter of said proximal end [Fig. 2], said head having a recessed cavity forming a regular polygon at the center for receiving a turning implement [0019].

As a preliminary matter, it may be seen that Pais is directed to a system for stabilizing a vertebral column by inserting a self-tapping expandable insert into the vertebral space between two adjacent vertebra to spread them apart. See Pais, col. 4, line 62 – 65 and col. 5, lines 3 – 6. Conversely, Applicant's invention is directed to a surgical screw that is directed to the fixation of

plates or other elements normally used in the recomposition (*i.e.*, healing) of proximately situated human bone structures [0010]. Since Applicant's invention is not intended to spread apart two adjacent bone structures, a person of ordinary skill in the art would not find Pais a useful reference when attempting to fix two bone structures for recomposition.

The Examiner rejected claim 1 over Pais, finding that Pais discloses a surgical screw comprising an expandable element comprising external threads that run along its length, and having slots 42 and 44. New claim 9 now recites an expandable element having a substantially cylindrical configuration comprising "a finely threaded external surface along the length of said cylindrical configuration, said threads being substantially continuous . . ." Support for this limitation is found in the specification at paragraph [0020] and in Figs. 1 and 2.

The external threads on the surgical screw of Pais are significantly different from those of Applicant's invention, as is suggested in the differing purposes for each described invention. Pais describes the external thread as follows:

> A self-tapping helical thread 46 extends about the periphery of the root i.e., the cylindrical outer surface 48 of the expandable member. The helical thread is interrupted at each slot. The helical thread tapers from its root, i.e., the cylindrical outer surface 48 to its apex 50, to form sharp, bone-cutting self-tapping edge. As will be discussed later, the height (i.e., distance from the root, i.e., the cylindrical outer surface 48 to the apex 50) of the self-tapping thread 46 is selected so that it will readily cut into the hard, cortical bone 16 of the opposed vertebrae, but not substantially into the softer, interior cancellous bone 18.

Pais, col. 5, lines 33 – 42.

> In order to expedite the cutting action into the hard, cortical bone, a pair of sharp starter notches 66 are cut into the threads and enable the threads 46 to readily begin to cut into the cortical bone 16 when the distal end of the expandable insert 26 is screwed into the intervertebral space 12 by the rotary force imparted by the tool 30.

Pais, col. 6, lines 31 – 37.

By contrast, the finely threaded surface of applicant's invention has no "sharp starter notches" nor a "sharp, bone-cutting self-tapping edge." A person of ordinary skill in the art

would not find the disclosure of Pais to suggest applicant's use of a "finely threaded surface" on which the threads are "substantially continuous." The distinction between the external self-tapping tapered helical thread of Pais and the finely threaded surface of Applicant's surgical screw is further emphasized by Pais' recognition of the same distinction in its disclosure of a "fine helical thread" that extends about the tapering outer surface of Pais' expanding screw (Pais, col. 5, line 53), which is inserted within the threaded bore of Pais' expandable insert.

The Examiner observed that Applicant's disclosure of "extremely close threads" is a relative statement, commenting that "relative to an auger, for example, the threads are extremely close." Claim 9 has restated this limitation by claiming a cylindrical configuration comprising a "finely threaded external surface along the length of said cylindrical configuration." This limitation is supported in all figures, and in paragraph [0020]. In determining the meaning of this claim language, one must acknowledge that the surgical screw of Applicant's invention is "destined to promote the fixation of plates or other elements usually normally used for the human body bone structures recomposition." Paragraph [0010]. A person of ordinary skill in the art would not confuse the description of an auger with Applicant's description of a finely threaded external surface on a surgical screw intended for implantation within a human bone. Rather, as is disclosed in all figures, the threads are "fine" with respect to the surface upon which they are situated, and are located "extremely close[ly]" together.

The Examiner also finds that Pais discloses a distal end having a trunk configuration. The distal end of Applicant's apparatus, as shown in Figs. 1, 2 and 3, forms a smooth conical frustum, that is, a conical surface that terminates (is truncated) at the axial bore, prior to the apex of the cone. The distal end of Pais, however, is not smooth and does not form a truncated conical surface. As shown in Fig. 6A, 6C, and 6F of Pais, the distal end terminates at two "sharp starter

notches" which enable the threads to readily begin to cut into the cortical bone at the distal end of the expandable insert. Pais, col. 6, lines 31 – 38. Pais does not anticipate a smooth conical frustum, but exhibits sharp notches that are intended to cut bone.

The Examiner also found claims 1 – 8 to be unpatentable for obviousness over U.S. Patent No. 2,381,050 to Hardinge in view of Pais. According to the Examiner, Hardinge teaches a screw as illustrated in Figs. 5 and 6 comprising a monoblock body with the body comprising a funneling bore. The Examiner further finds that Fig. 2 of Hardinge discloses threads along the entire length of the expandable member. A close inspection, however, reveals that Hardinge does not disclose external threading along the entire length of the expandable member. Rather, Fig. 2 of Hardinge discloses external threading along the length of the expandable member only up to an enlarged unthreaded section 6a which is described as: "an unthreaded section 6a which constitutes an abutment against which the nut structure 13 may engage when the nut is completely unscrewed to its outermost position." Hardinge, page 3, left column, lines 12 – 16. This feature is carried through in Figs. 3 – 5, leaving no figure, and no language in Hardinge, that discloses external threading along the entire length of the expandable member. Thus, although Hardinge does disclose some threading upon the external surface of the expandable member, Hardinge also teaches that the end of the expandable member should not be threaded, this feature providing a means for withdrawing the expandable member by unscrewing the tubular sleeve 13.

The Examiner acknowledges that Hardinge fails to disclose a bore having internal threading along its entire length, but refers to Paes as teaching a bore that is threaded interiorly along its entire length. However that may be, neither Hardinge nor Paes teaches a finely threaded external surface along the entire length of the expandable member. Moreover, neither

Hardinge nor Paes teaches using a finely threaded external surface to secure an expandable member within a bone structure.

The Examiner also notes that the distal end of the device of Hardinge comprises a trunk configuration, and that the slots extend approximately about one-half of the length of the expandable element. While these features are present in Applicant's surgical screw, the truncated conical frustum of Applicant's invention has four slots that separate four expandable members in four directions, rather than the two expandable members disclosed by Hardinge. This feature is produces spreading of the expandable members in all directions, making the final rotational positioning of the expandable element irrelevant with respect to the bone cavity in which such elements are to be expanded, with respect to the precise structure or configuration of the adjacent bone structures being fixated. In addition, Applicant's surgical screw has a cylindrical configuration of constant diameter throughout, thereby permitting Applicant's surgical screw to be completely embedded within a bone structure without requiring the formation of a bone cavity having multiple diameters, as is required by Hardinge. Similarly, although Pais recites a cylindrical body, that body has a large external helical self-tapping thread extending around it, the helical thread being intended to cut bone and to lodge the cylindrical body between two adjacent vertebra where it will act as a supporting wedge. A person of ordinary skill in the art would not find it obvious to combine the teachings of Hardinge and Pais to make Applicant's surgical screw.

The limitations of claim 9 would not have been obvious to a person of ordinary skill in the art at the time this application was filed, and patentably distinguish the invention of this application from the prior art cited by the Examiner. Accordingly, Applicant respectfully

requests the Examiner to withdraw his rejections and to enter a Notice of Allowance for claims 9 and 10 in light of the arguments presented herein.

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Respectfully submitted,

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APPENDIX:

UNITED STATES PATENT APPLICATION PUBLICATION

Pub. No. 2002/0147454 A1

Building configuration introduced in a surgical-use screw

to Aziz Rassi Neto